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September 3, 2008

The Honorable Mary Pat Thyng  
J. Caleb Boggs Federal Building  
844 North King Street  
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**REDACTED -  
PUBLIC VERSION**

Re: Roquette Freres v. SPI Pharma, Inc., et al., C.A. No. 06-540 (GMS)(MPT)

Dear Judge Thyng:

On behalf of Defendant SPI Pharma, Inc. ("SPI"), I write with background about the discovery dispute teleconference scheduled for this Friday, September 5, 2008 at 12:15 p.m. (D.I. 191).

The dispute concerns requests for the production of documents and inspection of testing equipment made by SPI on the record during the August 8 deposition of Roquette Freres' ("Roquette") technical expert witness, Dr. Harry Brittain, and subsequently memorialized in an August 11 letter to counsel for Roquette. (Exhibit A). As explained below, the requested documents and SPI's inspection of Dr. Brittain's laboratory equipment are relevant to SPI's noninfringement defense and affirmative counterclaim of invalidity based on indefiniteness.

The patent-in-suit claims a pulverulent mannitol having a friability of about 40% to about 80% when measured according to a "Test I" protocol. Dr. Brittain recently conducted a friability test on SPI's Mannogem™ EZ – one of the accused products – [REDACTED]

[REDACTED] SPI first became aware that Dr. Brittain conducted this experiment on the day of his deposition. SPI's counsel was handed at deposition a two-page lab notebook entry reflecting Dr. Brittain's recent experiment on Mannogem™ EZ, which was marked as Defendant's Exhibit ("DX") 38. (Exhibit B). DX 38 and the deposition testimony [REDACTED]

[REDACTED] attached hereto as Exhibit

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C). SPI immediately requested the manuals and literature associated with this instrumentation and an opportunity to inspect the equipment, but Roquette has consistently refused.

SPI should be provided with this limited discovery for all of the following reasons:

- Documents associated with the testing equipment should have already been produced by Roquette in response to SPI's Document Request Nos. 9 ("documents and things relating to...any testing...on the EZ product") and 11 ("documents and things relating to...any testing... relating to the subject matter of the patent-in-suit including, but not limited to, the test methods associated with 'Test I'");
- The requested documents and inspection of laboratory testing equipment are relevant in [REDACTED] This information further strengthens SPI's noninfringement defense and SPI is entitled to its production;
- At the heart of SPI's contention that the patent-in-suit is invalid for indefiniteness is the notion that the claims of the patent-in-suit lack specificity concerning the friability testing procedure. For example, the Test I protocol does not specify the type of drum to be used with the Erweka friabilator. [REDACTED]  
[REDACTED] The operating manual, instruction guide, and any and all documents associated with the equipment used by Dr. Brittain are thus highly relevant to SPI's indefiniteness argument;
- Roquette has already produced the Operating Instructions for the Hosokawa Powder Characteristics Tester (RF 1336-60, Exh. D), which Dr. Brittain used in measuring various properties of the accused products in this case. Roquette also has produced product literature concerning the Erweka friabilator (RF 500-01, DX 41, Exh. E attached hereto), but not the instructions or operating manuals. By doing so, Roquette acknowledged that documents associated with the testing equipment used to measure the various properties claimed in the patent-at-issue are relevant and responsive to SPI's document requests. Roquette should not be allowed to selectively determine which equipment documentation it will produce; and
- SPI made its request for the production of documents and things associated with Roquette's testing equipment in a timely manner. SPI's requests were made on the record during Dr. Brittain's deposition when it first learned that additional testing had been conducted. SPI memorialized its requests in writing on August

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11, well before the close of expert discovery on August 15. Roquette cannot deny SPI's requests on the basis of delay or because discovery has since concluded.

SPI respectfully asks Your Honor to compel Roquette to produce all documents concerning the Erweka friabilator and Gilson Ro-Tap used during Dr. Brittain's testing of the accused products, and allow SPI's counsel an opportunity to inspect this equipment at the earliest possible date.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'J. Castellano', with a stylized flourish at the end.

Jeffrey T. Castellano (No. 4837)

JTC:mmeeh  
Attachments

cc: Clerk, U.S. District Court (By Hand Delivery)  
Mary B. Graham, Esq. (By E-mail and Hand Delivery)  
Julia Heaney, Esq. (By E-mail and Hand Delivery)  
Douglas V. Rigler, Esq. (By E-mail)